IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	**Confirmation No. 2869**
Takuya WATANABE et al.	:	Attorney Docket No. 2004_0003
Serial No. 10/771,417	:	Group Art Unit 1647
Filed February 5, 2004	:	Examiner Bridget E. Bunner
NOVEL G PROTEIN COUPLED RECEPTOR PROTEIN, DNA AND ITS LIGAND	:	**Mail Stop: ISSUE FEE**

RULE 56 STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please place the attached copy of the Canadian Office Action dated July 24, 2006 from the corresponding Canadian Application No. 2,347,294 and the response thereto in the application file.

Respectfully submitted,

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Application No.	:	**2,347,294**
Owner	:	TAKEDA PHARMACEUTICAL COMPANY LIMITED
Title	:	**NOVEL G PROTEIN COUPLED RECEPTOR PROTEIN, DNA AND ITS LIGAND**
Classification	:	C12N 15/12 (2006.01)
Your File No.	:	**30179-1**
Examiner	:	R. Oulton

YOU ARE HEREBY NOTIFIED OF :

- A REQUISITION BY THE EXAMINER IN ACCORDANCE WITH SUBSECTION 30(2) OF THE *PATENT RULES*;
- A REQUISITION BY THE EXAMINER IN ACCORDANCE WITH SECTION 29 OF THE *PATENT RULES*.

IN ORDER TO AVOID **MULTIPLE ABANDONMENTS** UNDER PARAGRAPH 73(1)(A) OF THE *PATENT ACT*, A WRITTEN REPLY **TO EACH REQUISITION** MUST BE RECEIVED WITHIN **6** MONTHS AFTER THE ABOVE DATE.

This application has been examined taking into account the:

Description,	page 1-119, and pages 1-14 of the Sequence Listing as originally filed; a computer readable copy of the Sequence Listing, as received on May 14, 2001 during the national phase;
Claims,	pages 120 and 121, as originally filed; pages 122 and 123, as received on May 11, 2004 during the national phase;
Drawings,	pages 1-8, as originally filed; and page 9, as received on May 11, 2004 during the national phase.

This application has been examined taking into account applicant's correspondence on prior art received in this office on May 11, 2004.

The number of claims in this application is 29.

The claims are directed to a plurality of alleged inventions as follows:

Group A - Claims 1-12, 15, and 20 relating to the alleged G protein coupled receptor of SEQ ID NOs:1 and 5;
Group B - Claims 13, 14, 16, 17, and 21-29 relating to a ligand of the alleged G protein coupled receptor (said ligand including the KISS-1 polypeptide of SEQ ID NO:10); and
Group C - Claims 18 and 19 relating to a compound that alters the binding of the ligand to the alleged G protein coupled receptor.

The claims must be limited to one invention only as set out in section 36 of the *Patent Act*.

Please note that the authority regarding unity of invention for all patent applications filed in Canada, including PCT applications in the national phase is found in section 36 of the *Patent Act*. Since the requirements under section 36 of the *Patent Act* have the same scope as those prescribed under PCT Rule 13, these requirements are not different from or additional to PCT Rule 13.1, and therefore are compliant with Article 27(1) of the PCT.

In view of the above, a search of the prior art and examination have been limited to the subject matter in claims 1-12, 15, and 20 relating to the alleged G protein coupled receptor of SEQ ID NOs:1 and 5.

A search of the prior art has revealed the following:

References Applied:

Canadian Patent document			
CA2248222	Apr. 16, 1998	C12N 15/16	Bard, J.A. et al.
Publication			
GenBank ¤	Aug. 4, 1998	Acc. #AC005379	Lamerdin, J.E. et al.

¤ citation stemming from a foreign search report

Bard et al. disclose galanin receptor proteins and nucleic acid molecules encoding same. Specifically disclosed is the polypeptide of SEQ ID NO:4 that is 36.2% identical to amino acids 16-387 of SEQ ID NO:5 and 35% identical to amino acids 16-363 of SEQ ID NO:1 of the instant application. Further disclosed are vectors, host cells, methods, and antibodies relating to same.

Lamerdin et al. disclose the nucleic acid sequence of cosmid R32603, derived from human chromosome 19. Specifically disclosed is the nucleic acid molecule of accession number AC005379 (GenBank) that is 88% identical to nucleotides 736-1021, 88% identical to nucleotides 526-739, 89% identical to nucleotides 362-507, 81% identical to nucleotides 36-244 and 88% identical to nucleotides 247-371 of SEQ ID NO:2 of the instant application. Further, said nucleic acid molecule of accession number AC005379 is 99% identical to nucleotides 736-1197, 100% identical to nucleotides 1-244, 100% identical to nucleotides 504-739, 99% identical to nucleotides 362-506, and 100% identical to nucleotides 244-371 of SEQ ID NO:6 of the instant application.

The examiner has identified the following defects in the application:

Claims 1-5, 7-10, 15 and 20 do not comply with paragraph 28.2(1)(*b*) of the *Patent Act*. Bard et al. disclosed the claimed subject matter before the claim date. In view of the disclosed polypeptides "substantially the same" as SEQ ID NOs:1 and 5 of the instant application, the subject matter of these claims is anticipated by the disclosure of Bard et al.

Claims 4 and 5 do not comply with paragraph 28.2(1)(*b*) of the *Patent Act*. Lamerdin et al. disclosed the claimed subject matter before the claim date. In view of the sequence identity between the nucleic acid molecule disclosed by Lamerdin et al. and SEQ ID NOs:2 and 6 of the instant application, the subject matter of these claims is anticipated by Lamerdin et al.

Claims 7 and 8 do not comply with section 28.3 of the *Patent Act*. The subject matter of these claims would have been obvious on the claim date to a person skilled in the art or science to which they pertain having regard to Lamerdin et al. and common general knowledge. Vectors and host cells relating to known nucleic acid molecules would require no inventive ingenuity.

Claims 1-3 are broader in scope than the teaching of the description and do not comply with section 84 of the *Patent Rules*. The claimed "partial peptide" or sequences of "substantially the same amino acid sequence" could comprise proteins with a biological function unrelated to those of the instant application.

Claims 1 and 2 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. The inclusion of "substantially" causes ambiguity.

Claim 3 is indefinite and does not comply with subsection 27(4) of the *Patent Act*. The length of the contemplated partial peptide is not defined in the claim.

Claim 4 is indefinite and does not comply with subsection 27(4) of the *Patent Act*. The inclusion of the term "having" renders the claim indefinite. It is unclear if the contemplated polynucleotide comprises or consists of the recited sequence.

Claim 8 encompasses multi-cellular life forms, and is outside the definition of invention in section 2 of the *Patent Act*. (See Harvard College v. Canada (Commissioner of Patents), (2002) S.C.C. 76, or (2002) 21 C.P.R. (4th) 417). The claim refers to a "transformant".

Claim 8 is indefinite and does not comply with subsection 27(4) of the *Patent Act*. The contemplated "transformant" is not defined in the claim.

Claims 10 and 11 are broader in scope than the teaching of the description and do not comply with section 84 of the *Patent Rules*. The specification, in so far as it relates to claims 10 and 11, does not correctly and fully describe all of the claimed subject matter and its operation or use, so as to enable any person skilled in the art to practice the invention across the entire scope of the claim. The instant application does not disclose and characterize a neutralizing antibody. It follows that the specification does not comply with subsection 27(3) of the *Patent Act*.

Claim 12 does not comply with section 84 of the *Patent Rules* because there is insufficient support in the description for the claimed subject matter. The specification, in so far as it relates to claim 12, does not correctly and fully describe the claimed subject matter and its operation or use, so as to enable any person skilled in the art to practice the invention. The instant application does not disclose and characterize a diagnostic composition comprising an antibody. It follows that the specification does not comply with subsection 27(3) of the *Patent Act*.

Claim 12 is indefinite and does not comply with subsection 27(4) of the *Patent Act*. Applicant is claiming a composition without fully defining it in the claims. A composition contains at least two components (see Section 11.04 the Manual of Patent Office Practice), but applicant has only defined one. Applicant must define at least two components of the claimed composition. Further, the claim does not define the disease or condition to which the diagnostic composition relates.

Claims 15 and 20 are indefinite, and do not comply with subsection 27(4) of the *Patent Act*. Applicant is claiming a method without fully defining it in the claim. A method is a series of steps to be followed to achieve a desired result. The method does not contain an active step. All of the steps of the allegedly novel method must be defined in the claim.

Claim 15 is indefinite, and does not comply with subsection 27(4) of the *Patent Act*. The expression "the ligand" has no antecedent. Further, the expression "determining the ligand" lacks clarity and renders the claim indefinite.

Under section 76 of the *Patent Rules*, every trade-mark must be identified as a trade-mark. If "Sephadex" on page 111, is a trade-mark, it must be so identified.

In view of the foregoing defects, the applicant is requisitioned, under subsection 30(2) of the *Patent Rules*, to amend the application in order to comply with the *Patent Act* and the *Patent Rules* or to provide arguments as to why the application does comply.

Section 29 of the Patent Rules requisition

Under section 29 of the *Patent Rules*, the applicant is requisitioned to provide:

- identification of any prior art cited in respect of the United States Patent and Trademark Office, and European Patent Office applications describing the same invention on behalf of the applicant or on behalf of any other person claiming under an inventor named in the present application, and the patent numbers, if granted, subsequent to applicant's correspondence received on May 11, 2004 under paragraph 29(1)(*a*) of the *Patent Rules*.

To satisfy this requisition, applicant should provide all the preceding information or documents, or provide in accordance with subsection 29(3) of the *Patent Rules* a statement of reasons why any information or document is not available or known.

R. Oulton
Patent Examiner
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